

Remarks

Information Disclosure Statement

The Office has asserted that several of the references submitted with the Information Disclosure Statement on March 1, 2004 were illegible. Applicants have attached legible copies of the references along with a PTO form 1449. Applicants respectfully request that the Examiner initial the form and return the form to Applicants. A fee was paid when these reference were submitted on March 1, 2004. Therefore, it is believed that no additional fee is due; however, if a fee is due the Commissioner is authorized to charge our deposit account number 13-2490.

Applicants have not yet been able to obtain legible copies of the following references:

Hospital Infection Control Practices Advisory Committee, "Recommendations for Preventing the Spread of Vancomycin Resistance," *Infection Control Hospital Epidemiology*, 16:105-113 (1995).

"Bacteriological Ambient Water Quality Criteria for Marine and Fresh Recreational Waters," Ambient Water Quality Criteria for Bacteria, USEPA (1986).

Manafi, M., et al., "Rapid Identification of Enterococci with a New Fluorogenic-Chromogenic Assay," *Water Science and Technology*, 27(3-4):271-274 (1993).

Mooney, et al., "Testing the Waters, a National Perspective on Beach Closings," *Natural Resources Defense Council*, pp. 1-67 (July 1992).

Trepeta, R., et al., "Esculinase (β -glucosidase) for the Rapid Estimation of Activity in Bacteria Utilizing a Hydrolyzable Substrate, p-nitrophenyl- β -D-glucopyranoside," *Journal of Microbiology*, 53:273-277 (1987).

As soon as copies of these references are received Applicants will forward them to the Examiner's attention.

Rejection of Claims 33-47 Under 35 U.S.C. §101

Claims 33-47 stand rejected under 35 U.S.C. §101 as claiming the same invention as claims 1-13 of U.S. Pat. No. 6,355,449B1. This is a statutory double patenting rejection. Applicants respectfully traverse the rejection.

35 U.S.C. §101 prevents the issuance of two patents for the same invention. “Same invention” means identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1984); *In re Vogel* 164 USPQ 619 (CCPA 1970); *In re Ockert*, 114 USPQ 330 (CCPA 1957); MPEP §804. A reliable test for double patenting is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the cited patent. See *In re Vogel* 164 USPQ at 622; MPEP §840.

Claim 33 of the instant application recites:

A medium for detecting vancomycin-resistant Enterococci in a sample from a rectal swab, peri-rectal swab, or stool sample, comprising:

vancomycin in an amount sufficient to suppress the growth of vancomycin sensitive Enterococci;

a first nutrient indicator which is a substrate for a first bacterial enzyme and provides first detectable signal when cleaved by the first bacterial enzyme;

a second nutrient indicator which is a substrate for a second bacterial enzyme and provides a second detectable signal when cleaved by the second bacterial enzyme, wherein the second detectable signal is distinct from the first detectable signal;

an effective amount of one or more selective agents active to prevent or inhibit the growth of microorganisms other than Enterococci.

Claim 1 of U.S. Pat. No. 6,355,449B1 recites:

A medium for detecting vancomycin-resistant Enterococci in a sample from a rectal swab, peri-rectal swab, or stool sample, comprising:

vancomycin in an amount sufficient to suppress the growth of vancomycin sensitive Enterococci;

a first nutrient indicator which is a substrate for a first bacterial enzyme and provides a first detectable signal when cleaved by the first bacterial enzyme wherein the first nutrient indicator is a substrate for β -glucosidase;

a second nutrient indicator which is a substrate for a second bacterial enzyme and provides an intermediate molecule when cleaved by the second bacterial enzyme, and the intermediate molecule provides the second detectable signal upon reacting with a developing agent, wherein the second detectable signal is distinct from the


first detectable signal, wherein the second nutrient indicator is a substrate for pyrrolidonyl arylamidase;
an effective amount of one or more selective agents active to prevent or inhibit the growth of microorganisms other than Enterococci when a sample from a rectal swab, peri-rectal swab, or stool sample is introduced into the medium wherein the one or more selective agents are selected from the group consisting of: amikacin sulfate, polymyxin B, bacitracin, clindamycin, cefotaxime, amphotericin B, sodium azide, thallium acetate, nalixidic acid, enoxacin, cinoxacin, ofloxacin, norfloxacin, cefotaxime, gentamycin, neomycin, polymyxin B, colistin, and bile salts.

Claim 33 of the instant application is broader than claim 1 of the '449 patent. For example, claim 33 of the instant invention would be infringed by a medium that uses a first nutrient indicator that is not a substrate for β -glucosidase (assuming all other elements of the claim were present), while claim 1 of the '449 patent would not be infringed by a medium that uses a first nutrient indicator that is not a substrate for β -glucosidase (assuming all other elements of the claim were present). Therefore, claim 33 of the application could be literally infringed by a medium that uses a first nutrient indicator that is not a substrate for β -glucosidase without literally infringing a corresponding claim in the cited patent. Therefore, the two claims do not recite the same inventions because a claim in the application could be literally infringed without literally infringing a corresponding claim in the cited patent.

On the basis of the foregoing and in view of the arguments presented herein, reversal of the rejection is appropriate.

Respectfully submitted,

Date: 7/13/04

By: 
Lisa M. W. Hillman
Reg. No. 43,637